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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/446,783	05/16/2000	NEIL P. DESAI	VPHAR1460-2	2878

7590 12/03/2001  
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EXAMINER  
DEWITTY, ROBERT M

ART UNIT 1616  
PAPER NUMBER 8

DATE MAILED: 12/03/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

<b>Application No.</b> 09/446,783	<b>Applicant(s)</b> SOON-SHIONG ET AL.	
<b>Examiner</b> Robert M DeWitty	<b>Art Unit</b> 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1)  Responsive to communication(s) filed on 19 September 2001.
- 2a)  This action is **FINAL**.
- 2b)  This action is non-final.
- 3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4)  Claim(s) 1-52 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5)  Claim(s) \_\_\_\_\_ is/are allowed.
- 6)  Claim(s) 1-52 is/are rejected.
- 7)  Claim(s) \_\_\_\_\_ is/are objected to.
- 8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9)  The specification is objected to by the Examiner.
- 10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12)  The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14)  Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a)  The translation of the foreign language provisional application has been received.
- 15)  Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1)  Notice of References Cited (PTO-892)
- 2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3)  Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4)  Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5)  Notice of Informal Patent Application (PTO-152)
- 6)  Other:

**DETAILED ACTION**

Claims 1-65 are presently pending in the instant application.

***Claim Rejections - 35 USC § 102***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 45-46 and 48-52 are rejected under 35 U.S.C. 102(e) as being anticipated by Desai et al (U.S. Pat. No. 5,916,596).

The invention taught in \*\*596 was invented by Desai, Tao, Yang, Louie, Zheng, Yao, Soon-Shiong, and Magdassi. The invention provides the in vivo delivery of insoluble active agents in the form of suspended particles coated with protein. The anti-drug Taxol can be embodied in the form of nanoparticles in a liquid dispersion or a solid which can be easily reconstituted for administration (col. 6, lines 56-59). Delivery can occur by oral, intravenous, subcutaneous, intramuscular, inhalation, topical, or transdermal methods.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 1-44 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Desai et. al., further in view of Langer.

Desai, as discussed above, does not teach dosage amounts.

Art Unit: 1616

Langer teaches the infusion of paclitaxel at 135 mg/m<sup>2</sup> and 200 mg/m<sup>2</sup> by 1 hour infusion. Langer concludes that higher doses of formulation yield intolerable toxicity, and the protocol was limited at paclitaxel doses exceeding 215 mg/m<sup>2</sup>.

One with ordinary skill in the art would have been motivated to make particles comprised of Taxol for in vivo delivery in order to obtain to a formulation for in vivo delivery of Taxol at a higher concentration for increased or more effective response, while at the same time limiting or reducing the toxicity of the active agent.

### ***Response to Arguments***

3. Applicant's submission of Abstract is acknowledged.
4. Applicant's arguments filed 9/13/01 have been fully considered but they are not persuasive based on the following reasoning:

Applicant's argues that the patent \*\*596 is not "by another". Specifically, because Desai, Soon-Shiong, and Magdassi are named inventors on the instant application and \*\*596, \*\*596 can not be considered prior art.

"By another" is defined when an inventive entity is different, i.e., not all inventors are the same (MPEP 2136.04). The inventors listed on \*\*596 include, in addition to Desai, Soon-Shiong, and Magdassi, Tao, Yang, Louie, Zheng, and Yao. Therefore, \*\*596 is invented "by another" and can be considered valid prior art.

The rejection under 35 U.S.C. 102(e) is maintained.

Regarding the rejection under 35 U.S.C. 103(c), as indicated above, \*\*596 is valid prior art because it is invented by another. Applicant in addition argues that

Langer is not valid prior art because of Applicant's claim of priority to 60/051,021. U.S. Patent and Trademark Office records show that the inventors listed on \*\*021 are Desai and Soon-Shiong. Thus, Applicant's claim to priority to \*\*021 is denied as the invention is "by another", and the date of the filing of \*\*021 is inapplicable.

The application of the teachings of Langer are thus valid, and the rejection under 35 U.S.C. 103(c) is maintained.

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M DeWitty whose telephone number is 703-308-2411. The examiner can normally be reached on 9:00am - 5:00pm.

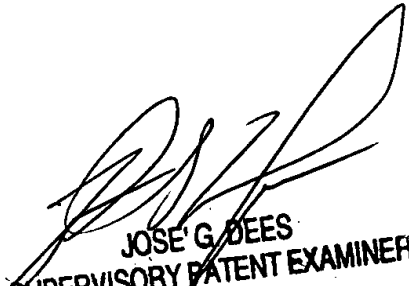
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4527. The fax phone numbers for

Art Unit: 1616

the organization where this application or proceeding is assigned are 703-308-7924 for regular communications and 703-308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

RMD  
November 21, 2001

  
JOSE G. DEES  
SUPERVISORY PATENT EXAMINER  
1616